510(k) Summary for the MEDICREA® INTERNATIONAL LigaPASS

1. GENERAL INFORMATION

510(k)	Traditionnal
Date Prepared	December 05, 2013
Trade Name	LigaPASS
Common Name	✓ Bone Fixation Cerclage, Sublaminar
Classification Name	✓ Bone Fixation Cerclage per OWI 888.3010
Class	Class II
Product Code	OWI
CFR section	888.3010
Device panel	Orthopedic
Legally marketed predicate devices	Universal Clamp Spinal Fixation System (Zimmer Spine)= K110348 LigaPASS (MEDICREA INTERNATIONAL) = K112736
Submitter	MEDICREA International 14 Porte du Grand Lyon 01700 Neyron, France
Contact Person	Audrey VION 14 Porte du Grand Lyon 01700 NEYRON FRANCE +33(0)4 72 01 87 87 E-mail : avion@medicrea.com

DEC 06 2013

2. PREDICATE DEVICE DESCRIPTION

The Universal Clamp System (K110348) and LigaPASS (K112736) are temporary orthopedic implants intended to provide stabilization during the development of solid bony fusion and aid in the repair of bone fractures. The Universal Clamp System (K110348) and LigaPASS (K112736) are designed to be incorporated into constructs and used in conjunction with other medical implants.

The indications for use for the Universal Clamp System (K110348) include, but are not limited to, the following applications: Spinal trauma surgery; Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult scoliosis, kyphosis and, spondylolisthesis; Spinal degenerative surgery, as an adjunct to spinal fusions.

The indications for use for the LigaPASS (K112736) include, but are not limited to, the following applications: Spinal trauma surgery, Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis; Spinal degenerative surgery, as an adjunct to spinal fusions.

The Universal Clamp System (K110348) and LigaPASS (K112736) may also be used with other medical implants made of titanium or cobalt chrome alloy whenever "wiring" may help secure the attachment of other implants.

3. DEVICE DESCRIPTION

The LigaPASS connectors connect a rod to a vertebra. These connectors can independently tighten the rod and the bone anchor. The LigaPASS connectors are composed by a connector body, a rod set screw, a locking set screw for the band and a polyester band.

4. INTENDED USE

The ligapass is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilziation as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. LigaPASS system is indicated for the following applications:

- Spinal trauma surgery, used in sublaminar,or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 10 years of age and older, adult scoliosis, and kyphosis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;

5. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

MEDICREA® INTERNATIONAL LigaPASS is substantially equivalent to the ZIMMER SPINE Universal Clamp® System (K110348), in terms of intended use, materials used, mechanical safety and performances.

Device	Universal Clamp® System (ZIMMER SPINE)	LigaPASS
510(k) number	K110348	In progress
Intended use		
	The Universal Clamp System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include, but are not limited to, the following applications: Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques; Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis; Spinal degenerative surgery, as an adjunct to spinal fusions; The universal Clamp System may also be used in adjunction with other medical implants made of titanium alloy whenever "wiring" may help secure the attachment of other implants.	The ligapass is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilziation as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. LigaPASS system is indicated for the following applications: - Spinal trauma surgery, used in sublaminar,or facet wiring techniques; - Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 10 years of age and older, adult scoliosis, and kyphosis; - Spinal degenerative surgery, as an adjunct to spinal fusions; LigaPASS system may also be used in conjunction with other medical implant grade implants made of titanium or cobalt chrome alloy whenever "wiring" may help secure the attachment of other implants.
Design		
Components	Connector with polyester band: To circle a vertebra as a bone anchor and connect to a Ø5.5mm or Ø6mm rod.	Connectors with polyester band: To circle a vertebra as a bone anchor and connect to a Ø5.5mm or Ø6mm rod.
Range	A connector and a band.	Connectors and a band.
Materials		

Device	Universal Clamp® System (ZIMMER SPINE)	LigaPASS
	Universal clamp system is made from titanium alloy conforming to ASTM F136 or ISO 5832-3, with the exception of the band which is manufactured from polyethylene terephtalate (PET) and pure titanium conforming to ASTM F67.	LigaPASS connectors are made from titanium alloy conforming to ASTM F136 or ISO 5832-3, with the exception of the band which is manufactured from polyethylene terephtalate (PET) and pure titanium conforming to ASTM F67.

Material composition is identical to other MEDICREA® INTERNATIONAL products that have been cleared via the 510(k) process.

6. NON-CLINICAL TEST SUMMARY

The LigaPASS submitted by MEDICREA in this 510(k) includes components that have been approved by the FDA in the previous 510(k) (K112736) for the following indications:

The LigaPASS is a temporary implant for use in orthopedic surgery on skeletally mature patients. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

- Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal
- deformities such as scoliosis, kylphosis, spondylolisthesis;Spinal degenerative surgery, as an adjunct to spinal fusions;

The LigaPASS may also be used in conjunction with other medical implants made of titanium or cobalt chrome alloy whenever "wiring" may help secure the attachment of other implants.

The purpose of this new submission is to extend the indications for use to idiopathic and neuromuscular scoliosis treatment in patients 10 years of age and holder. No other changes in terms of design characteristics, principles of operation, packaging, sterility, biocompatibility or mechanical performances have undergone.

Mechanical testing of the MEDICREA® INTERNATIONAL LigaPASS implants was conducted following the ASTM F1717 *"Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model"* and following the ASTM F1798 *"Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanism and Subassemblies Used In Spinal Arthrodesis Implants"* to characterize their mechanical properties. These data was compared to the mechanical performance for other devices cleared for surgical fixation of the skeletal system (LigaPASS, MEDICREA INTERNATIONAL, K112736).

Accordingly, the mechanical performance of MEDICREA INTERNATIONAL LigaPASS implants has been established via these cleared devices (LigaPASS, MEDICREA INTERNATIONAL, K112736).

7. CLINICAL TEST SUMMARY

No clinical studies were performed.

8. CONCLUSIONS: NON-CLINICAL AND CLINICAL

The LigaPASS is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Medicrea International
Ms. Audrey Vion
Regulatory Affairs Manager
14 Porte du Grand Lyon
01700 Neyron
France

Re: K132395
Trade/Device Name: LigaPASS
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: OWI
Dated: November 7, 2013
Received: November 12, 2013

Dear Ms. Vion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____K132395_____
Device Name: LigaPASS

INDICATIONS FOR USE

The LigaPASS is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. LigaPASS system is indicated for the following applications:
- Spinal trauma surgery, used in sublaminar,or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 10 years of age and older, adult scoliosis, and kyphosis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132395